Tiger Team
Draft Transcript
June 15, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good afternoon and welcome, everybody, to the third meeting of the Privacy & Security Tiger Team. This is a public call. There will be opportunity at the end of the call for the public to make comment. Deven McGraw?

Deven McGraw - Center for Democracy & Technology – Director
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Paul Egerman?

Paul Egerman – eScription – CEO
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Latanya Sweeney? Gayle Harrell?

Gayle Harrell – Florida – Former State Legislator
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Josh Lemieux?

Josh Lemieux – Markle Foundation – Director, Personal Health Technology
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Either Judy Faulkner or Carl Dvorak? David McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
David Lansky? Dixie Baker?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Micky Tripathi? Neil Calman?

Neil Calman - Institute for Family Health - President & Cofounder
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Rachel Block? Christine Bechtel?

Christine Bechtel - National Partnership for Women & Families – VP
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
John Houston? Wes Rishel? Joy Pritts? Adam Green?

Adam Green – Progressive Chain Campaign Committee – Cofounder
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Did I miss anyone? Okay, Deven and Paul.

Paul Egerman – eScription – CEO
Great. Well, thank you very much and thank you to all of the work of the Tiger Team members for participating in this, our third call. We're doing these calls very rapidly and I very much appreciate the significant amount of time that this is taking and your involvement.

For the members of the public who may be listening to this call, we're certainly very pleased that you're interested in our work and we want to explain to you that we are a Tiger Team, which means we're sort of a small group of people that come from both the Policy Committee and the Standards Committee. We were formed to make some very rapid progress on a number of privacy and security issues, really for the month of June and over the months of July and August. We report to the HIT Policy Committee and we will be making our first formal recommendations on June 25th at the Policy Committee Meeting at that time.

The way we are going about this project that you will see in today's agenda is sort of a dual track. The dual track is we're dealing with some real world, technical issues that come about from a group of people that is working on dealing with NHIN Direct and then we, at the same time, are working on a much more generalized policy framework document and so on today's call you'll see I'm going to very briefly review what's called the Draft Recommendations, which is a result of last week's call to make sure people know that that exists, but then we're actually going to call our attention on this call to the framework discussion. Deven's going to lead that discussion. Then we will have another meeting on, I believe, it's a week from today, June 22nd. Do I have that right?

Deven McGraw - Center for Democracy & Technology – Director
That's correct.

Paul Egerman – eScription – CEO
Yes, June 22nd at 10:00. That runs for three hours?

Deven McGraw - Center for Democracy & Technology – Director
10:00 to 1:00.

Paul Egerman – eScription – CEO
10:00 to 1:00; where we're going to try to complete the Privacy & Security Framework Document and our recommendations in advance of the June 25th meeting next week. So that's the rough schedule.

To very quickly go through the Draft Recommendations, did we put those up on slides or not? I got a little confused, Deven, with the final—

Deven McGraw - Center for Democracy & Technology – Director
Yes, I think they have them if we want to use them. Yes, there they are.

Paul Egerman – eScription – CEO
Okay. What I'm going to do; I don't know that I can control this from here. Perfect. Exactly where I want to be; is quickly review what you see on your screen. The way we approached the technical side was we're looking at the issue of what you see in the first sentence, message handling, as was suggested actually from Micky Tripathi. We broke it into four categories: When there is no intermediary involved. The second one is when there is an intermediary that only does routing and has no access to PHI. The third one was an intermediary can open the message, but doesn't change the data. The fourth category was when they change the data.

Then based on these four categories we made some specific recommendations, which are on the next slide. Basically we said any exposure to PHI is a big deal and so then we felt it was less important to talk about how many data elements or the nature of the exposure in terms of what data elements are exposed. Just the fact that even a patient name was exposed, we figured that was enough to be like a trip wire. We said if there's no exposure that's a best practice, but if there is exposure what we suggested was that basically you need a business associate agreement.

In the event that in this midst of this associate agreement ... we should preclude the retention of the data or the reuse of the data, reuse of the data, of course, being the sale of the data by an intermediary. We didn't say what would happen if the intermediary, the HIO, actually did retain data for our … data. That will be something that we will be discussing probably in the month of July, so there is a sentence there that says we may make further privacy policy recommendations in the future on that issue.

If you go on to the next slide, basically, we also addressed an issue about credentials, which really ... something called digital certificates—

Deven McGraw - Center for Democracy & Technology – Director
Well, that's one form of credentialing, right, the digital certificates?

Paul Egerman – eScription – CEO
Yes. The context of what we were looking at was message handling and credentialing for message handling.

Deven McGraw - Center for Democracy & Technology – Director
Right.

Paul Egerman – eScription – CEO
There might be other ways of doing it, but that's sort of the basic concept. Then we put forward an idea that basically it's an interesting concept on one side that we say we wanted to retain the relationship between the patient and provider, so we said the provider is still responsible for maintaining the privacy of the record, including making sure that anybody they send a document to is authorized, is the right person; that you've done that correctly.

Then we also say providers can delegate that though; that we didn't expect providers to be personally responsible for making sure the credentials were right and they could delegate that responsibility to trustworthy organizations, which would be organizations that would operate under federal and state rules or guidelines.

Those were the two sort of basic –

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Excuse me. Would that eliminate their liability by contracting? Because you can't really contract away your liability I wouldn't think. Could you?

Paul Egerman – eScription – CEO

Yes. That's a good question. Let me answer that question and make another comment. First, my answer to that question is I'd give you an analogy. It's sort of like when a physician or a business owner signs like their tax return. You know, at the bottom of it they say, "I'm personally responsible that this tax return is correct." In point and fact, everybody uses an accountant or a CPA or somebody to fill that thing out. You never just fill the tax return out. That's sort of the analogy. I mean you're still responsible for getting it right. What you're really responsible for doing is having somebody trustworthy that handles it for you. That is what you're responsible for doing.

But in answering that question the other comment I want to give you is sort of like the ground rules we set for this is these documents were sent out to everybody. What we don't want to do in this call is spend a lot of time like wordsmithing it or reviewing the issues. So the purpose of going through this all is to make sure that people know that this is really our first important deliverable and the way we want you to go about this is ... your e-mails. It's on your screen.

If you have questions you should send e-mail questions to Deven and me about it. If you want to wordsmith it or change it because it's unclear or you disagree with it you should go ahead and do that, but we should do that though by sending e-mails to everybody. Then when we get to our meeting a week from today we'll do our best to compile all of those and do that all in one shot in terms of if people want to adjust it. What you're seeing here is our draft summary of what we heard on Friday and so that's how I'm asking you to respond; to either red line it, to put whatever questions or comments or disagreements you have and we will then spend some time in our meeting a week from today and make sure that everybody is on board with it.

Having said that, assuming everyone is okay with this process—

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Paul Egerman – eScription – CEO
I'm sorry. Was there a question there?

Deven McGraw - Center for Democracy & Technology – Director
I think that's Judy in the background.

Paul Egerman – eScription – CEO
Okay. So let me turn the meeting back to you, Deven, so you can start talking about some framework.

Deven McGraw - Center for Democracy & Technology – Director
Okay. Great. Thank you. Thank you very much, Paul. Hopefully we will get whatever concerns or feedback that you need to provide on this document. I just want to reinforce that because unfortunately, since we are trying to do this in order to be able to respond to the time constraints, we're doing it rather quickly, which does mean we hope that people will spend some time in between of the calls, especially since this call is particularly short, to provide us with some feedback. That's going to be very helpful.

So the next piece of this, consistent with our dual tracks that we're pursuing, is this NHIN policy and technology framework. It's the grid document that was distributed to you all and Judy re-forwarded it. We had asked for some folks to begin populating it and commenting on. I took a stab at populating the initial draft and then I had a couple of members send me some additional comments. In particular you'll see that Carol Diamond and the folks from Markle provided some help based on the common framework to populate some of this. Ideally, we will. There is a lot in here and so we're not always going to have time on these calls to go through this in detail, so I'm going to continue to implore you to take a look at this and do some red lining on it for me so that when we present it to the Policy Committee for them to review and to provide us their feedback on it it's at least in a shape where the members of the Tiger Team believe it's sort of our best initial effort.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Deven, this is David. Is it entitled Draft of 6/10? Is that the one –

Deven McGraw - Center for Democracy & Technology – Director
Yes. It says Draft 6/10. The heading across the top is The NHIN Policy & Technology Framework. It begins, really, on the first page with an articulation of, on one side, the policy principles, which were adopted by ONC and which are part of the strategic work plan that was put before the Policy Committee at its meeting in May. Then it also has, on the right-hand side, the technology principles that were endorsed by the Standards Committee after its adoption and implementation framework in the fall of last year. So these are sort of it begins the document with the over arching set of principles to guide the work and then essentially as you turn the page it enunciates each of the policy principles; on the left-hand side individual access, correction, etc. You can sort of see them going down.

Then, because principles, they provide the sort of outer boundaries for establishing policy, but it's not nearly enough to say individuals should be able to access their record, for example. What does that mean in terms of the rights and responsibilities of those providers and patients? What is the set of broader policy expectations, the broader policies that would need to be in place in order to articulate that principle?

Then reading across from there, what are sort of the best practices that need to be adopted? Then the next column is what particular technology requirements ought to be in place in order to support those policies? What are our mechanisms for enforcing those particular policies or best practices and sort of ... and enforcement comes accountability and oversight. In some respects this is going to be what we have in current law already, but in some respects it may be something that's not addressed very well in current law and we need to think about other mechanisms, such as meaningful use criteria, certification, data partner sharing agreements. There are sort of multiple ways to get at enforcing and holding people accountable for abiding by baseline policies, as well as best practices.

Then we added, per earlier request, a comment section where people could ask questions that would help us to continue to flesh this out.

So I think we've got a good basis here, but we still need some additional work to be done on it, but while we have the time I think we should start going through this. Rather than start with individual access, because one thing that I have not done is I have gone ahead and taken any comments that I got from folks. I just accepted them and incorporated them into one document. So, for example, if I look at individual access I think there may be some policies and practices on here that are relevant, but I'm not sure whether they're in the right category. Actually, on that note, it's not for me to decide. This is a workgroup document, so why don't we just start with individual access, which is the first section of this?

Again, the policy expectation is that providers and I put record holders just because, obviously, we're talking about a universe that's broader than providers depending on how you define it, but I'm open to wordsmithing this. Providers should provide individuals with prompt, electronic access to and copies of their health information at a reasonable cost. That's sort of a broad policy prescription that is not at the level of detail that says how much is reasonable and what do we mean by prompt, but I think that's where you start is with what's the expectation and then what are the practices that will need to be adopted more specifically.

So, for example, we have some populating the practice requirements with prohibitions on unauthorized use. Clearly, that's a practice. I'm not sure, Josh, I don't know if you want to because I know some of these come from the common framework and so forgive me for putting you on the spot since you're on the line for Carol, but can you tell me why the breech notification policy, for example, is in the individual access principle versus the security piece or one of the others?

Josh Lemieux – Markle Foundation – Director, Personal Health Technology
Well, it may depend on how the access is being executed. If the access is provided directly from the provider through some secure access site to the individual patient that's sort of one data stream to

develop policies for. If there are intermediaries or this is being delivered through some type of Web based service that is commercial or something and information is being passed and aggregated then that implies a broader set, perhaps, of policies. So our division for how the access takes place is going to help determine which of the policies make sense or are required.

The documents that we're drawing from are meant to be a fairly comprehensive framework, as you know, for the circumstance where an individual is having some services to aggregate their information and that they may be collecting that information across multiple data sources.

Deven McGraw - Center for Democracy & Technology – Director
Right. Like a PHR, for example.

Josh Lemieux – Markle Foundation – Director, Personal Health Technology
Like a PHR.

Deven McGraw - Center for Democracy & Technology – Director
Okay.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Deven, I have a question. This is Dixie Baker.

Deven McGraw - Center for Democracy & Technology – Director
Sure, Dixie. Hello.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
What are those blue things and the number references, like T8, CP2?

Deven McGraw - Center for Democracy & Technology – Director
Yes. Those are, I think, links to the Markle common framework. Is that right, Josh?

Josh Lemieux – Markle Foundation – Director, Personal Health Technology
Yes.

Deven McGraw - Center for Democracy & Technology – Director
Okay.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Links to references? What are they supposed to do?

Josh Lemieux – Markle Foundation – Director, Personal Health Technology
Well, they're documents. The collaborators at Markle spent a great deal of time looking at the landscape of individual access to electronic personal health information—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. Excellent work. Excellent work.

Josh Lemieux – Markle Foundation – Director, Personal Health Technology
So each one of those documents has specific recommended practices that a great number of organizations agree to, including provider groups, health insurers, new technology consumer brands, lots and lots of people. So whether that should go into this being a table with very narrow width we were just pointing to some things for reference. It's not necessarily saying that that would have to be in this document. These are things to think about when the individual is getting access. So maybe we should spend a second to talk about what kind of use case we're talking about with individual access with NHIN Direct.

Deven McGraw - Center for Democracy & Technology – Director
Right.

Josh Lemieux – Markle Foundation – Director, Personal Health Technology
Is this as simple as if a message about you is sent from one party to another you might be able to log in to your own account and have access to a copy of that message? Is that what the vision is?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David. I am working aggressively on the NHIN Direct. I think the simplest idea would simply be that the provider or holder of the record send the copy using Direct to the patient.

Josh Lemieux – Markle Foundation – Director, Personal Health Technology
... yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
They could do that as a CC, just like in an ordinary e-mail, but there would not be a repository of data that had been sent on your behalf or anything like that. There are no side effects; it's just a direct message.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
But this is not supposed to be limited to NHIN Direct, right?

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Yes.

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Right.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I agree. I was just answering the question.

Deven McGraw - Center for Democracy & Technology – Director
You're right, Dixie. I started off by thinking of this in terms of directed exchange, because obviously, the exchange mechanism that is being used raises different risk levels and different issues per our previous discussions. But folks did point out on an earlier call that there are sort of a set of baseline policies that need to be applicable to exchange regardless of the model. Then there are probably some particular policies and practices that would need to be put in place that meet the specific risks raised by the mechanism of exchange. Right? Is that a fair articulation of sort of where we were? We might have to actually have, maybe in the comment section of this matrix, point out where there are certain practices that are either exclusive to or more likely to be helpful for different types of exchange.

Gayle Harrell – Florida – Former State Legislator
This is Gayle. I want to get into the personal health records. Where does this fit into that and what kind of additional safeguards are we going to look at or are we on personal health records when the provider is sending information to that and what happens at that point to that information? Are we going down that path or can you give me some direction as to how this integrates into the subject of personal health records?

Deven McGraw - Center for Democracy & Technology – Director
Okay. I can. Thank you, Gayle. That's a good question. So I see this as I think you're right; it's intended to be an over arching policy framework, but depending on how the principle is, I did sort of populate this with the expectation that it's a framework that gets to, at least initially, how providers in the traditional healthcare system are responsible for protecting data, sharing data with individuals, etc. So I didn't think about it in terms of when I began to populate it, as Paul Egerman said, when I drew first blood on this document in terms of thinking about the policy expectations I wasn't necessarily thinking about PHR providers specifically. I'm wondering whether we ought to.

It's an issue that has come up in our Privacy & Security Workgroup and it's a big one. There's currently an ongoing study that HHS has out with a contractor in the field and I wonder whether that's one of those. What are the protections that apply to PHRs that need to be unique from those that are applicable to the healthcare system, if that's not an issue that needs to be done by the Tiger Team over the summer. Paul, have you—?

Paul Egerman – eScription – CEO
It's a good question.

Deven McGraw - Center for Democracy & Technology – Director
Wait. I can't hear you.

Paul Egerman – eScription – CEO
I said the question you're asking is a very good question and it really goes to the scope of our work because we're really doing is privacy and security around exchange. Our initial focus is also exchange involving the HIEs or HIOs, because that is where ONC has the most. It's just a tactical issue, Gayle. The funding has occurred for these things and people are asking questions and we want to make sure there are answers to the questions. So I guess my answer, my response to you is that the EHR is a good issue and in some sense what we're doing here, we're laying the ground work for a lot of that talk, so when we talk about individual access and some of these things, like an audit trail, that it impacts PHRs just like it impacts everybody else, that those are important concepts. But right now it's on the edge of our radar screen. Our radar screen right now is really exchange of information with the impact of intermediaries or HIOs and HIEs in that process so that we can get that part off the ground over the summer.

Neil Calman - Institute for Family Health - President & Cofounder
This is Neil. I have a question because I'm trying to understand how this would work. So if we're using NHIN Direct to send a message I want to, as a patient, request a copy of my record from my provider. Two questions: First of all, does that include all of the third party information that my providers collected from everybody else, hospital records, other things that they may have as my medical home?

And second of all, how do I read this stuff? I mean if we're sending it in an encrypted format what do I need on my computer at home to be able to read this information that's being made accessible to me because it's not coming through my EHR or anything? What do I need to be able to read it?

Paul Egerman – eScription – CEO
Let's do the questions one at a time. The first one is the question of individual access, just what do you get access to. You get access to everything ... summary – is that what I understand your first question is?

Neil Calman - Institute for Family Health - President & Cofounder
Yes. Is it a summary? Is it my mental health records if I want them? Is it everything? I mean what are we doing? Because we talked about that whole issue of segmentation. We haven't gotten to it yet, but what am I asking for? I want access to everything that exists about me anywhere. How do I get that? Is that what we're talking about?

Paul Egerman – eScription – CEO
That's the first question; not to interrupt you; which is a great question. I mean I'll sort of, to use my expression, draw blood by saying it seems to me that our approach to that was heavily towards the consumer or towards the patient. We'd say the patient should have the right to get all of the data -

Neil Calman - Institute for Family Health - President & Cofounder
Right.

Paul Egerman – eScription – CEO
I mean so maybe that's what we should say, although that has an implication on the technology side because right now there isn't really a standard for producing the entire record. There's only a standard for producing a summary document. But that would be one answer. I don't know if somebody wants to answer that differently in terms of what – because it's not just an issue of access. I think it's electronic access and it's in a machine readable form, right?

Neil Calman - Institute for Family Health - President & Cofounder
In a readable format. I think I could then ... a format that I could read.

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Yes.

Neil Calman - Institute for Family Health - President & Cofounder
I want access to it myself as a patient. I don't want to go through some other third party to give it to me.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Speaking from the NHIN Direct perspective, the model is one of provider initiated push in response to a request from the patient –

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Right.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Or perhaps as a standing request that you work out with your patient where you say at the end of every encounter I will send a message to you summarizing the encounter. That's the core use case. Anything could be sent, including the entire record, although that would be a cumbersome process once you have a large record. But the fundamental assumption is the provider makes a decision and pushes the data to the patient. That certainly does not cover all of the use cases where the patient needs to have access to their record. I think there are many other ways, including portals and etc. that would come into effect when the patient wants to do a pull of data.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think ... this within the context of NHIN Direct makes it overly complex and at the same time is restrictive at the same time. But to respond to Paul's comment, I think it is access, that patients should be given electronic access to all of the information that any one provider may have. I think that's important because we don't want to impose a requirement on a provider that that provider be responsible for knowing every place that that patient may have information.

Paul Egerman – eScription – CEO
That's right, Dixie. It seems like the provider should not be expected to give information they don't have.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Right.

Paul Egerman – eScription – CEO
Well, I mean you could ask them to chase and find it, but that doesn't seem fair –

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes.

Paul Egerman – eScription – CEO
And so I was trying to answer Neil's first question by simply saying all data. The patient has a right to get all data.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
What I'm suggesting is that you add to that. I agree with you, Paul, but that you clarify that that's all of the data that that provider has.

Paul Egerman – eScription – CEO
Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I certainly agree with that. I was just, again, trying to explain what NHIN Direct is all about—

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Right.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Because it keeps coming up and it is a request that we address those needs, so NHIN Direct is not the mechanism for access to all of the data. It's a mechanism to get a specific thing triggered by the provider, like a—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The other point that I wanted to make is that when we discuss regarding the comment about whether it's in human readable or etc., we also discussed that within the Standards Committee and concluded that it should be both, human readable, as well as computer readable so that it has to be something that a user would understand, but also something that could be forwarded to their PHR and be incorporated into the PHR.

Paul Egerman – eScription – CEO
Okay. So then you're suggesting that the answer to Neil's question is all of the data that the provider has, that provider's record, should be available either in a human readable form or in a machine readable form, whichever the patient wants?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. But that also requires that you have to have the electronic capabilities that the provider has; it has to be interoperable and compatible with all PHRs out there.

Paul Egerman – eScription – CEO
That's right. There's a technology requirement to do this last one. The last part about the machine readable, the technology requirement is there has to be a standard to produce that machine readable form. All of the provider's responsibility should be would be to purchase a computer system that produces the records in machine readable format according to the standards.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
It's a little bit more complicated. There is the content standard, which is what the readability comes from and then there's some kind of a transport standard, which is a way to move it to the consumer and then there's an access standard, which is how the consumer logs in and gets access to it. All of those would have to be worked out to make this general purpose.

Paul Egerman – eScription – CEO
Right. So then what we should do though is list those as the technology requirements.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes. Agreed. And for content standards we're in pretty good shape with the CCR, CCD. Those are—

Paul Egerman – eScription – CEO
Yes, but those are actually record summaries. Those are not complete records.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Agreed. Although, they will be the dominant thing that's exchanged in the short term since they're required for meaningful use, so we've got to make those work.

Judy Faulkner – Epic Systems – Founder
This is Judy –

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That doesn't really respond to the total access we're trying to—

David McCallie – Cerner Corporation – Vice President of Medical Informatics
No. No. It's necessary. It's not sufficient.

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Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Sufficient is everything. I agree.

Paul Egerman – eScription – CEO
I'm sorry. Judy was trying to break in.

Judy Faulkner – Epic Systems – Founder
Yes. Are we saying that all of the data collected needs to be available to the patient, every single bit?

Paul Egerman – eScription – CEO
That was what I said and no one disagreed.

Deven McGraw - Center for Democracy & Technology – Director
There was not always room to get in the conversation flow there.

Judy Faulkner – Epic Systems – Founder
Yes. I worry about that for several reasons. One is that right now with the access that patients have to the data there are systems that are usable out there that translate what the doctor means to what the patient can read it as. In other words, they have much more patient friendly terminology for certain things. It's going to be very difficult for patients to understand a lot of it if it isn't converted into patient friendly stuff. Things such as for lab test results; if you just put up lab test results by themselves they're not nearly as helpful as if you put them out with interpretations that are sold by companies that say what they mean. Is it normal? Is it not normal?

The same thing for diagnoses. What does that mean? If you have just simply an episode in the hospital that might run to, if you printed it, hundreds, if not thousands of pages because you have so much data there.

Deven McGraw - Center for Democracy & Technology – Director
Judy, essentially the way that I would augment Paul's comment is whenever the patient has a right under the law to have today, and quite frankly, if they want the pages and pages of documents from the hospital record, if it's clinical information and it's part of what they're entitled to have under HIPAA and it's not restricted per either some federal provision or state provision, then in my opinion it's not our job to say the patient doesn't want or doesn't need the reams of hospital data if they ask for it.

Now, having said that, I totally agree with you that it's not going to be terribly useful to too many people without some sort of translation or some easier mechanism, but certainly, in looking at this we've been told that if you just open up the access the innovators will come in and create the tools that can help

consumers to use it rather than us sort of regimenting that patients can't get it unless there's a tool that helps them understand it, because that, to me, creates obstacles.

Judy Faulkner – Epic Systems – Founder
Yes. You're right, Deven. They will come in and do more to help with it, although let me ask it a different way too. Should they be seeing every data element or just those data elements – in other words, software will keep lots of data elements that it creates. Are they to see all data elements or just the data elements that the doctors see? In other words, there are data elements in there that are just for the purpose of making sure that everything is done right.

Deven McGraw - Center for Democracy & Technology – Director
I'm not sure I'm following you, Judy. What's a data element as you're talking about it?

Judy Faulkner – Epic Systems – Founder
Maybe it's a time lapse between when the doctor entered this and when that was done. So the system may, behind the scenes, be keeping elapsed times behind the scenes—

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Or keeping all of the audit trail information ... access ...

Judy Faulkner – Epic Systems – Founder
Yes. Audit trail and stuff like that.

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... ages of the record were accessed.

Judy Faulkner – Epic Systems – Founder
Exactly.

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All of that kind of stuff that's captured. The time, in minute and second, of every entry.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I think the spirit of the HIPAA regulation is consistent with standard disclosure property practices, so what can be disclosed legally of the record under court order or whatever is the kind of thing we're talking about here, not the housekeeping database stuff.

Judy Faulkner – Epic Systems – Founder
Okay.

Paul Egerman – eScription – CEO
You know who could help us in this discussion? I guess it's unfortunate John Houston is not on the call, but in all organizations there's usually people who run what used to be called the medical records function, the health information.

W
It's the release of information people, the ROI people.

Paul Egerman – eScription – CEO
Yes. They actually know both, the legal stuff and what is normally released. I suspect they actually have written guidelines and everything as to what we release because on the one hand what you're really saying, Judy, is very interesting. In some sense I'm saying all data, so the question is what is the definition of all. There is all data. You don't really mean all data, because there is a lot of stuff that physicians don't see when they look at a record.

Judy Faulkner – Epic Systems – Founder
The other thing is if you mean all data do you mean it in a way that is really readable or not readable? In other words, you could have all of the machine numbers that are interfacing in from whatever machines this person is attached to in the inpatient environment and do you really mean that they should be just rows of numbers or are we talking about almost a whole new system that allows them to see it in a way that makes meaningful sense out of it? Because if it doesn't make meaningful sense it's not as useful, but if it does that technology may not exist yet. In other words, there are displays that are there for the doctor, but are we then saying that we have to use the same software that we may display lab tests to in an interactive way to a doctor, also in an interactive way to a patient?

Paul Egerman – eScription – CEO
Well, that's a good question. Certainly—

Deven McGraw - Center for Democracy & Technology – Director
Someone is trying to jump in I think.

Josh Lemieux – Markle Foundation – Director, Personal Health Technology
Yes. Deven and Paul, the phrase that Judy just mentioned, meaningful sense, brought me back to meaningful use. The question is how much of what we're doing is tied to meaningful use, because if it is and there's already been a great deal of thought and prioritization given to priority data types or meaningful use and the content packages ... that could be used. If there's a consensus among this group that that's what we need to be really focusing policy towards to sort of prime the pump of consumer access as part of an NHIN Direct health information exchange maybe that can focus our conversation back and away from everyone in ... in every system that we're on right now.

Paul Egerman – eScription – CEO
Yes. That may be a good way to prioritize it, but as Deven pointed out, under HIPAA you have the right to the chart, all of it.

Josh Lemieux – Markle Foundation – Director, Personal Health Technology
You have a right to everything that's in the electronic health record.

Paul Egerman – eScription – CEO
Right. Which is, these days, all of it.

Deven McGraw - Center for Democracy & Technology – Director
Right, but I think it's a good point. I mean I raised the HIPAA point before, but we can, as a set of recommendations, begin with the data that is required to be made available to patients or provided to them directly, even not necessarily upon request, as the sort of first order to prime the pump. I like that phrase. I mean there are certainly legal obligations under HIPAA and that data, the data that you might provide a patient under meaningful use, is not necessarily the entire amount that you might need to provide under HIPAA, but it certainly is with respect to a recommendation that we could make an excellent start beyond where we are today.

Josh Lemieux – Markle Foundation – Director, Personal Health Technology
I think that's why the summary record, the CCD, CCR has been the focus of most of the use cases and NHIN Direct. For that exact reason that's what's required for meaningful use and it is a nice summary for the patient.

W
So are we really talking about something meaningful to the patient, like the record you just mentioned, which I think makes perfect sense? Are we talking about more of a legal obligation, that a patient who asks for everything should get it? That's not been standardly made available.

Neil Calman - Institute for Family Health - President & Cofounder

I think that we talked like about five different things. We've talked about PHRs. We've talked about portals. We've talked about this HIPAA requirement, if people have legal access to their full records. We've talked about sending people some messages after each encounter. I think rather than lumping all of this stuff together I think these things are going to have to be looked at sort of individually. They all have different characteristics in terms of what information is available, but also probably in the way that it's most meaningfully transported to people so that it can be used by them.

M
Right. I would throw one more angle into that. Neil, I agree with that need to break it down.

One other angle is that just because the consumer is asking for it doesn't mean that it should be necessarily translated into "consumer friendly terms," because some consumers are quite sophisticated about their own health and some consumers want to use that data to transfer it to other physicians and they don't want to have it converted into consumer speak. They want it as technical as they can be, which is not to say that everyone wants it that way, but if I had an exercise tolerance test done I want the actual report so that I can provide it to my other doctor, rather than just a summary of it in consumer friendly terms that tells me I'm normal or something.

Paul Egerman – eScription – CEO
Let me see if I can summarize what I'm hearing. What we're saying is people agree with the word all or all that's required by law, but we really need to define all a little bit better. Especially we need to define it in the context in which it's asked because if we've got a patient discharged from the hospital it's not necessarily the case that you want every ... every half hour on that patient that you have to provide that five years from now. So maybe we just have to say this word all in the context in which the data is asked for, that's an issue that we need more discussion on.

Deven McGraw - Center for Democracy & Technology – Director
Yes.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I wanted to say I think that's exactly the right question and I wanted to respond to Judy's comment about information that is not visible to the physician. I don't think a consumer should ever have access to information that's not available to the provider.

M
So here's what I want—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
From a liability perspective it's nothing else.

M
Yes. I totally agree.

Paul Egerman – eScription – CEO
Let me throw out a suggestion to this issue. We're going to answer Neil's question with "all" with quotes around it. We're going to say that we're going to have to provide some other mechanism to define all and that maybe Deven and I reach out to some of these HIN people and see if they can help us, because maybe some of this has already been done.

Deven McGraw - Center for Democracy & Technology – Director
Yes.

Paul Egerman – eScription – CEO
And to see if that could help us.

Deven McGraw - Center for Democracy & Technology – Director
Yes.

Paul Egerman – eScription – CEO
I also wanted to make sure that in responding to this we didn't lose the comment that David made, which is to do this in a machine readable way has some technology requirements and he listed all three things. There has to be content standards. There has to be transport standards. He said the third thing, access standards. Right? Did I hear you right, David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes, Paul. That's the word I used. I couldn't think of anything better, but what I mean by that is some means to navigate and find this stuff, a Web browser interface or some such standard way to get to it.

Deven McGraw - Center for Democracy & Technology – Director
Okay.

Paul Egerman – eScription – CEO
So I don't have any problem with the first two, but the third one, access standards, that is something a little bit different because we've never said before that these systems have to have a portal so that patients can access the data. I mean certainly basically the way we're defining individual access, that would be reasonable and useful. You could save a huge amount of grief for the physicians; instead of answering questions they just tell the patient to log on and look at it and ... yourself if you want. You know? Maybe they'd probably say it better than that, better than I just said it, but I mean that's the whole concept of self service. But I'd just make an observation that if we say that there is an access standard that's putting forward a new technology requirement for the EHR that we haven't put forward before.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It's presentation I think is what he's talking about, like getting back to the point of we know that ARRA requires that the physician or the provider be able to transfer electronically their EHR to a PHR vendor if the user requests that.

Paul Egerman – eScription – CEO
Yes, but the issue is—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
... access ... content ... transport, but at the same time, if a user requests an electronic copy of their record you don't want them to be able to push some electronic bits that can't be viewed in either PDF or Word or something that a person would understand, so that kind of presentation comes into play.

M
... my observation is that it's a new requirement.

Deven McGraw - Center for Democracy & Technology – Director
Yes and I'm not sure. Do we want to do one size fits all like that? I mean I think it's tempting to go down into that level of detail, but I think initially setting out some broader issues to address is much more productive and otherwise we're going to probably spend the next four and a half hours on individual access; not on this call, but—

W
No, we're not.

W
... I think—

W

We are not going to do that.

Deven McGraw - Center for Democracy & Technology – Director
No we're not.

W
We don't have the time to do that.

W
Deven, I think we need to go back on what is the purpose of this. I'm hearing multiple different things, which, first of all, it's a legal purpose. Secondly, it's an I want to look in my record purpose. What are we trying to accomplish here? Maybe that will help us figure out what we should be doing.

Deven McGraw - Center for Democracy & Technology – Director
Okay.

Paul Egerman – eScription – CEO
Well, part of what you're trying to accomplish though is, again, to get back to message handling and exchange with intermediaries, we want to lay out the rules, so individual access will impact those intermediaries who have a centralized record.

W
But are we really trying to have the person who wants to look at the basic information about their health versus the person who wants to look at the entire stream of all of the blood pressures collected for three days running while he or she was in the hospital?

Deven McGraw - Center for Democracy & Technology – Director
Why wouldn't we want to help both people?

W
That's why I'm trying to figure out what our goal is here. To me, as I read this, as a principle of individual access we should pick one of those, which one it is, because I think they are really two very different things. The one that has all of the stream of everything in it, there is currently no way to show that to somebody in a readable form. So if that's the way we want to go then we have different technology challenges than if it's the other way, which is show the person the basic information about his or her record.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Well, I think I totally agree with Deven that we don't want a one-size-fits-all. That was not my intent. What I think we do want to do is to make sure that the information is usable. You can't just fire bits at them—

M
Right.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It's got to be usable.

(Overlapping voices.)

Judy Faulkner – Epic Systems – Founder
... want it usable and you want it done in a reasonable amount of time. There is so much data in there that nobody has written pose to make all of that stuff usable except in certain kinds of displays that might be, say, an EKG going across your screen. The numbers are captured, but it's not—

Paul Egerman – eScription – CEO

Let me make a suggestion, Judy. I understand what you're saying. We've only got a few minutes left on this call. I said that we would do all data. I'm going to propose changing the word all to complete, so we're going to give patients the right to the complete record of their data—

M
How about maybe a clinical record, a complete clinical record?

Paul Egerman – eScription – CEO
A complete clinical record. Then we may have to have a discussion on what's the definition of that.

Judy Faulkner – Epic Systems – Founder
I think even within that you have to discuss that—

Paul Egerman – eScription – CEO
Yes.

Judy Faulkner – Epic Systems – Founder
Because I think you're going to find that almost all doctors say that doesn't make sense.

Paul Egerman – eScription – CEO
Okay.

Josh Lemieux – Markle Foundation – Director, Personal Health Technology
I would propose an even sharper distinction. It seems like we need to have a policy discussion on individual access related specifically to meaningful use and the phase one vision for that. Then we need a policy discussion along the Recovery Act provision that talks about individuals having the right to get their information in electronic format and that's not tied to ... meaningful use or priority ... that's .... We could have two separate discussions along those lines and the latter gets more towards the sort of what is all or what is complete that we could try to work on and come up with something reasonable.

Paul Egerman – eScription – CEO
Okay. So Deven and I will organize that, these follow-on discussions –

Deven McGraw - Center for Democracy & Technology – Director
Yes.

W
... that we've not talked about on that same conversation, it has to do with some legal implications of what you're releasing and the timeliness in which you're releasing it. So there are liability issues and also there are things where different states require physicians to see data, specifically lab data, before it's released to patients.

Paul Egerman – eScription – CEO
Yes. We will handle that.

Deven McGraw - Center for Democracy & Technology – Director
Yes.

W
You also have to make sure that that is appropriately put within that category of the timeliness of when things are released.

Deven McGraw - Center for Democracy & Technology – Director
That's—

W
Then you also have to look at psychiatric records.

Joy Pritts – ONC – Chief Privacy Officer
This is Joy and this has been a really fascinating discussion and I think it's been very useful. I am a little concerned as we're having this discussion that we are kind of having it in a way that is going to extend this conversation and this discussion well beyond the dates in which we need some decisions made on some of the other key issues.

Deven McGraw - Center for Democracy & Technology – Director
Yes. Joy, I see where you're going. I think Paul and I need to have an off-line conversation about this framework approach and a sort of staged – it's occurring to me that if we have these deep dive conversations for each of these categories we really won't be able to get to some of the specifics in the way that we've been able to make progress on and that we might just try to sort of set a framework and a schedule for the later deep dives versus running the risk of getting really deep in the weeds. But I think Paul and I need to talk about how we could structure that.

Joy Pritts – ONC – Chief Privacy Officer
I think this is an important discussion and I think it needs to be had—

Deven McGraw - Center for Democracy & Technology – Director
Absolutely.

Joy Pritts – ONC – Chief Privacy Officer
Maybe it needs to be held later on; maybe rearranging some of the discussion would be helpful, because I know that these are very important issues. Believe me, I've always been ... patient access to health information. You know that. But, the more pressing needs that have been described to us are fairly more basic. I mean we don't have a way of authenticating patients yet in order to even give them access.

Deven McGraw - Center for Democracy & Technology – Director
Right.

Joy Pritts – ONC – Chief Privacy Officer
So there are some issues here that, really, all of these issues need to be discussed, but I think we really do need to sit back and prioritize a little bit in order to kind of meet some of their needs a little bit.

I also wanted to tell you all that I ran into Arian this morning and he was quite pleased with what he had seen coming out of this group. That was an unsolicited comment from him. He just voiced that he thought you guys were doing a really great job in framing things at the right level that were helpful for him to do what he needed to get done.

M
That's all relative. It's just based on what he experienced in Redmond.

Paul Egerman – eScription – CEO
Hey, listen. We got a compliment. Let's go with it.

W
I'm taking it. I'm taking it.

Paul Egerman – eScription – CEO
I just wanted to go with a compliment, so we'll go with the compliment.

W
... the secret of life is lowering your expectations.

Judy Faulkner – Epic Systems – Founder
I love what Joy just said. I think getting back to the basics of figuring out what we really have to do is the only way we're ever going to make the date. We may be trying to do too much at once.

I want to throw in one more thing you have to think about, which is the timing. What about a patient who, five years later, wants to look at the data—

Deven McGraw - Center for Democracy & Technology – Director
Okay. Okay. Stop.

Judy Faulkner – Epic Systems – Founder
... everything it's getting to be awfully busy.

M
Here's another way to frame this as it relates to what Joy's request is, again, to think about the intermediaries and think about these HIOs and think about the ones that have centralized or aggregated data. Maybe the issue is what level of patient access do those organizations have to provide. It's a narrower question –

W
Yes. Again, I am still hoping that we can set some guardrails at the broader level before we start carving this up into little pieces.

M
Okay.

W
That's just a piece.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO
Would it be too tactical or just too confusing to try to focus it on sort of meaningful use transactions?

M
I think that's too limited.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO
Too limited. Okay.

M
In my opinion it's too limited because, for example, meaningful use doesn't do anything about radiology right now, so patients don't have access to their radiology interpretations. That's an odd thing.

W
But are they supposed to have access to their interpretations or to the x-rays themselves?

M
Yes.

W
That's a whole, huge picture.

M
It is a huge picture.

Paul Egerman – eScription – CEO

So anyway, we'll take that—

Deven McGraw - Center for Democracy & Technology – Director
We need to open this up to public comment and we've got three minutes.

Paul Egerman – eScription – CEO
Right. So Deven and I will take all of this into consideration.

Deven McGraw - Center for Democracy & Technology – Director
Yes.

Paul Egerman – eScription – CEO
We'll be meeting again on Tuesday. I'm going to make a few comments before we open to the public. We need to get on Tuesday. We couldn't today. I think we might ask you to think about the issue also of correction, assuming that we figure out what they can access. There are a number of issues there.

W
I'm sorry. Paul, I feel fairly strongly about this. I'm going to have to jump in. We cannot have another discussion on Tuesday on access because—

Paul Egerman – eScription – CEO
Yes. I wasn't proposing that.

W
Okay.

Paul Egerman – eScription – CEO
I was not proposing that.

W
Okay. Thank you.

Paul Egerman – eScription – CEO
As I said, I was asking people to think a little bit about the issue of correction and I assume that we got access already figured out.

W
Okay.

Paul Egerman – eScription – CEO
The other thing I want to ask everybody to do and remind everybody to do is to read through the recommendation to make sure that that's right, that you're comfortable with every word and that if you have any things that aren't quite right about it or changes to respond to that by e-mail to see if we can get any adjustments to that done by e-mail before next week's meeting.

Deven McGraw - Center for Democracy & Technology – Director
Yes. That's important.

Paul Egerman – eScription – CEO
Having said all of that wonderful stuff, why don't we open to see if there is any public comment?

Judy Sparrow – Office of the National Coordinator – Executive Director
Great. Operator, could you see if anybody from the public cares to make a comment, please?

Thank you. Just one other announcement: Thursday, June 17th, Dixie is hosting her final Webinar on consent. Mike Davis from VA will be making a presentation. I believe I sent all of you a calendar invite, but if not, all of the information on dialing in is on the ONC Web site.

Operator, anybody waiting?

Operator
We do not have any comments at this time.

Judy Sparrow – Office of the National Coordinator – Executive Director
Okay. Thank you.

W
Wow! They've already lost interest and it's only meeting three.

M
We've stunned the public.

Deven McGraw - Center for Democracy & Technology – Director
Thank you, everybody. Stay tuned.

Public Comment Received During the Meeting

1. See HIPAA definition of Designated Record Set.

3. Is there consideration of approving existing NIST certification, such as FIPS 140-2 on hardware encrypted devices, as acceptable security certification in relation to section 13402 of the HITECH Act so that medical facilities, patients' PHRs, etc. can utilize their grant funding on appropriate technology and begin integration immediately?